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| EXAMINER | |
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| SAIDI, AZADEH | |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

HH

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/824,941 | LEE ET AL. | |
| | Examiner | Art Unit | |
| | Anita Saidi | 3735 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *26 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-86* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-50 and 52-86* is/are rejected.

7)☒ Claim(s) *51* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :5/7/07, 3/3/05, 2/14/05, 7/19/04.

## DETAILED ACTION

### *Claim Rejections - 35 USC, § 112, 6TH Paragraph*

1. A claim limitation will invoke 35 U.S.C. 112, sixth paragraph, if it meets the following 3-prong analysis:

(A) The claim limitations must use the phrase "means for " or "step for"

(B) The "means for " or "step for " must be modified by functional language;

and

(C) The phrase "means for " or "step for " must not be modified by sufficient structure, material or acts for achieving the specified function.

Where means plus function language is used to define the characteristics of a machine or manufacture invention, such language must be interpreted to read on only the structures or materials disclosed in the specification and "equivalents thereof" that correspond to the recited function.

Claims 81-86 invoke 35 U.S.C. 112, sixth paragraph, as they meet the three prong tests above; therefore the following claim limitations are being treated as invoking 35 U.S.C. 112, sixth paragraph.

For art rejection purposes the claim limitations:

In ref to claims 81-86:

a. *Means for acquiring a respiration waveform*

*b.* *Means for detecting characteristics*

c. *Means for generating a marked respiration*

d. *Means for transmitting information*

e. *Means for displaying the waveform*

f. *Means for storing information*

Have been interpreted as covering the following respective corresponding structures described in the specification:

a. Sensor, such as transthoracic impedance sensor, or the use of patient-external respiratory bands, respiration flowmeter measurements, implantable or patient-external breath sound detection, blood oxygen levels, and/or other processes

b. Processor (431)

c. Waveform system (235)

d. Communication circuitry (450)

e. Computer screen or other type of display

f. Memory circuit (460)

***Claim Interpretations***

2. In light of 112, 6th paragraph invocation, the claims are rejected on prior art as best understood.

**Note:** In view of the aforementioned, an absence of a prior art rejection of any claim(s) should not be taken as an indication of allowable subject matter unless otherwise

indicated.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 1-4, 6-7, 22-24, 28-29, 30-37 are rejected under 35 U.S.C. 102(e) as being anticipated by US pub. No. 2004/0102814 to Sorensen et al (Hereinafter "Sorensen").

In reference to claims 1-3:

A method for characterizing respiration of a patient, comprising:

Acquiring a respiration waveform (184 & ¶ 13); detecting one or more characteristics associated with the respiration (¶ 50); and generating a marked respiration waveform using the respiration waveform and one or more symbols indicating the one or more characteristics associated with the respiration (Fig. 4), wherein at least one of acquiring, detecting, and generating is performed implantably (Fig. 1 & ¶ 68).

In reference to claim 4:

The acquiring the respiration waveform comprises sensing transthoracic impedance (Fig. 3 & ¶ 22).

In reference to claim 6:

The detecting the one or more characteristics associated with the respiration comprises detecting one or more physiological conditions (¶ 7).

In reference to claim 7:

The detecting the one or more characteristics associated with the respiration comprises detecting one or more non-physiological conditions (¶ 29).

In reference to claim 22:

The detecting the one or more characteristics associated with the respiration comprises determining respiration rate (¶ 7 & 29).

In reference to claim 23:

The detecting the one or more characteristics associated with the respiration comprises determining respiration volume (¶ 29).

In reference to claim 24:

The detecting the one or more characteristics associated with the respiration comprises determining minute ventilation (¶ 47).

In reference to claims 28 and 29:

The generating the marked respiration waveform comprises aligning the one or more symbols relative to the respiration waveform, the aligning the one or more symbols relative to the respiration waveform comprises aligning a particular symbol relative to the respiration waveform to indicate a time of occurrence of a particular respiration characteristic (¶ 65 & 66).

In reference to claims 30 and 31:

The acquiring one or more additional waveforms (Fig. 4), wherein generating the marked respiration waveform comprises generating the marked respiration

waveform using the one or more additional waveforms and time aligning the respiration waveform and the one or more additional waveforms (¶ 65).

In reference to claim 32:

The acquiring the one or more additional waveforms comprises acquiring a physiological waveform (Fig. 4, ECG, V Pressure).

In reference to claim 33:

The acquiring the one or more additional waveforms comprises acquiring a non-physiological waveform (¶ 29 & 54).

In reference to claim 34:

The acquiring the one or more additional waveforms comprises acquiring a cardiac waveform (Fig. 4).

In reference to claim 35:

Transmitting information about at least one of the respiration waveform, the one or more characteristics associated with the respiration, and the marked respiration waveform (¶ 15).

In reference to claim 36:

Displaying the marked respiration waveform (Fig. 4).

In reference to claim 37:

The storing information about at least one of the respiration waveform, the one or more characteristics associated with the respiration, and the marked respiration waveform (¶ 13).

6. Claims 1, 8-9, are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 6,890,306 to Poezevera (Poezevera).

In ref to claims 1 & 8-9:

A method for characterizing respiration of a patient, comprising:

Acquiring a respiration waveform (Fig. 1 & Col. 4, lines 7-13); detecting one or more characteristics associated with the respiration (Col. 2, lines 51-57); and generating a marked respiration waveform using the respiration waveform and one or more symbols indicating the one or more characteristics associated with the respiration (Fig. 1), wherein at least one of acquiring, detecting, and generating is performed implantably (Col. 2, lines 23-34). The generating the marked respiration waveform comprises generating the marked respiration waveform in response to the triggering event, the triggering event comprises a disordered breathing event (c & d in Fig. 1).

7. Claims 38, 49-50, 65-66, 68-70, 73-77 & 81-83 rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 6,928,324 to Park et al (Hereinafter "Park").

In reference to claims 38 and 81:

A system for characterizing respiration of a patient, comprising:

A respiration waveform sensor (202) configured to acquire a respiration waveform; a respiration processor (460) configured to determine one or more characteristics associated with the respiration (Col. 14, lines 20-30); and a waveform generator (Col.8, lines 38-52) coupled to the respiration waveform sensor and the respiration processor, the waveform generator configured to generate a marked respiration waveform comprising the respiration waveform and symbols indicating the one or more characteristics associated with the respiration (Col.8, lines 38-52), wherein at least one of the respiration waveform sensor, the respiration processor, and the waveform generator comprises an implantable component (202).

In reference to claims 49 & 50 & 73 & 74 & 82:

The respiration processor comprises a trigger circuit configured to detect a triggering event, wherein generation of the marked respiration waveform is activated in response to the detection of the triggering event. The respiration processor comprises a disordered breathing processor configured to detect

disordered breathing; and the triggering event comprises the detection of the disordered breathing (Col. 8, lines 38-65 & Col. 21, lines 30-43).

In reference to claims 65 and 66:

The one or more characteristics associated with the respiration comprises a respiration rate and respiration volume (Col. 4, lines 32-36).

In reference to claims 68 & 69 & 70:

The one or more characteristics associated with the respiration comprises expiration slope & expiration volume (Col. 8, lines 38-52).

In reference to claims 75-77 & 83:

The waveform generator is configured to acquire one or more additional waveforms, such as cardiac waveform (Col. 12, lines 63-65 & Col. 13, lines 1-9).

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1& 5, 10-12, 14-17 & 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,540,732 to Testerman (Hereinafter "Testerman") and in view of US Pub. No. 2002/0193839 to Cho et al (Hereinafter "Cho '839").

In reference to claims 1 and 5:

Testerman teaches:

A method for characterizing respiration of a patient, comprising: Acquiring a respiration waveform (Col. 2, lines 47-50 & Figs. 2a-2c of Testerman); detecting one or more characteristics associated with the respiration (32, 33,34,110, 112, 113 & 114 of Testerman); wherein at least one of acquiring, detecting, and generating is performed implantably (Col. 2, lines 54-67 of Testerman). The acquiring the respiration waveform comprises sensing airflow (Fig. 2 b & Col. 4, lines 25-30 of Testerman).

However, Testerman does not teach that:

Generating a marked respiration waveform using the respiration waveform and one or more symbols indicating the one or more characteristics associated with the respiration.

Cho '839 teaches:

An implantable medical device that includes a therapy component, a minute ventilation sensing circuit, and computational circuitry coupled to

the therapy component and the minute ventilation sensing circuit. The minute ventilation sensing circuit produces minute ventilation values indicative of a minute ventilation of the patient at time intervals. The computational circuitry detects an onset of sleep in the patient when the deviation of the minute ventilation values from the central tendency is less than a predetermined minute ventilation threshold value, and signals the therapy component to modify the therapy when the onset of sleep is detected in the patient (¶ 20 of Cho '839). Cho '839 also discloses forming a histogram of the deviations of the minute ventilation values received during the time intervals from the central tendencies; locating a pair of peaks in the histogram; and selecting an minute ventilation value residing between the peaks in the histogram as the minute ventilation threshold value (Claim 23 & Figs. 6&7 of Cho '839), Cho '839 also discloses that the histograms are stored in the CPU (204 of Cho '839) which is in communication with the programming unit (112 of Cho '839). The present invention claims that the marked waveform is generated but not displayed, and the system of Cho '839 is capable of performing the same (¶ 68).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to have included the markers and descriptions similar to that of Cho '839 to the implanted impedance sensing circuit of Testerman in order to add more information to the displayed respiratory graphs so that the sleep apnea diagnosis and study would be easier.

In reference to claims 10 -12 & 14 -17:

Detecting one or more characteristics associated with disordered breathing (Abstract of Testerman), detecting a duration of the disordered breathing (Fig. 4C of Testerman) and determining a type of the disordered breathing (Col. 1, lines 21-30 & Col. 2, lines 54-58 of Testerman).

In reference to claims 25-27:

The detecting the one or more characteristics associated with the respiration comprises determining one or more morphological features of the respiration waveform, comprises determining one or both of inspiration duration and expiration duration (Col. 4, lines 16-25 of Testerman) and determining one or both of an expiration slope and an inspiration slope (Col. 6, lines 13-28 of Testerman).

10. Claims 1 & 10, 12-21 & 41-42,44,46-48 & 52-64, 67, 71-72, 78 & 80, 84, 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 6,641,542 to Cho et al (Hereinafter "Cho '542") and in view of US Pub. No. 2002/0193839 to Cho et al (Hereinafter "Cho '839").

In ref to claim 1:

Cho '542 teaches:

> A method for characterizing respiration of a patient, comprising: Acquiring a respiration waveform (Col. 7, lines 2-3); detecting one or more characteristics associated with the respiration (Col. 7, lines 33-40); wherein at least one of acquiring, detecting, and generating is performed at least in part implantably (Fig. 2).

However, it does not teach:

> Generating a marked respiration waveform using the respiration waveform and one or more symbols indicating the one or more characteristics associated with the respiration.

Cho '839 teaches:

> An implantable medical device that includes a therapy component, a minute ventilation sensing circuit, and computational circuitry coupled to the therapy component and the minute ventilation sensing circuit. The minute ventilation sensing circuit produces minute ventilation values indicative of a minute ventilation of the patient at time intervals. The computational circuitry detects an onset of sleep in the patient when the deviation of the minute ventilation values from the central tendency is less than a predetermined minute ventilation threshold value, and signals the therapy component to modify the therapy when the onset of sleep is detected in the patient (¶ 20 of Cho '839). Cho '839 also

discloses forming a histogram of the deviations of the minute ventilation values received during the time intervals from the central tendencies; locating a pair of peaks in the histogram; and selecting an minute ventilation value residing between the peaks in the histogram as the minute ventilation threshold value (Claim 23 & Figs. 6&7 of Cho '839). Cho '839 also discloses that the histograms are stored in the CPU (204 of Cho '839) which is in communication with the programming unit (112 of Cho '839). The present invention claims that the marked waveform is generated but not displayed, and the system of Cho '839 is capable of performing the same (¶ 68).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to have included the markers and descriptions similar to that of Cho '839 to the implanted impedance sensing circuit of Cho '542 in order to add more information to the displayed respiratory graphs so that the sleep apnea diagnosis and study would be easier.

In ref to claims 38-40 & 81:

A system for characterizing respiration of a patient, comprising:

A respiration waveform sensor (210 & 510-2 of Cho '542) configured to acquire a respiration waveform; a respiration processor (310 of Cho '542) configured to

determine one or more characteristics associated with the respiration (¶ 34 of Cho '542); and a waveform generator (420) coupled to the respiration waveform sensor and the respiration processor, the waveform generator configured to generate a marked respiration waveform comprising the respiration waveform and symbols indicating the one or more characteristics associated with the respiration (Col. 8 ,lines 46-55 of Cho '542), wherein at least one of the respiration waveform sensor, the respiration processor, and the waveform generator comprises an implantable component (Col. 3, lines 15-23 of Cho '542).

In ref to claim 41:

At least one of the respiration waveform sensor, the respiration processor, and the waveform generator are wirelessly coupled to an external device (350 of Cho '542).

In ref to claim 42:

A component of at least one of the respiration waveform sensor, the respiration processor, and the waveform generator is mechanically coupled to a cardiac rhythm management device (Fig. 1 of Cho '542).

In ref to claim 44:

The respiration waveform sensor comprises a transthoracic impedance sensor (510-2 of Cho '542).

In ref to claim 46:

Sensing system configured to sense one or more conditions associated with the respiration (Col. 8, lines 46-80 of Cho '542).

In ref to claim 47:

The sensing system comprises a physiological sensor (530 & 540 of Cho '542).

In ref to claim 48:

The sensing system comprises a non-physiological sensor (520 of Cho '542).

In ref to claim 52:

The one or more characteristics associated with the respiration comprises oxygen de-saturation (530 of Cho '542).

In ref to claim 53:

The one or more characteristics associated with the respiration comprise one or more characteristics of a pulmonary disease (Col. 7, lines 33-46 of Cho '542).

In ref to claims 10 & 54:

The one or more characteristics associated with the respiration comprise a type of disordered breathing (410 & 420 of Cho '542).

In ref to claims 12-21 & 55 - 63:

The type of the disordered breathing comprises central & obstructive disordered breathing; mixed central and obstructive disordered breathing; hypopnea; . Cheyne-Stokes respiration; periodic breathing; sleep disordered breathing (Col. 1, lines 24-53 & Col. 6, lines 52-65 & 410 & 420 of Cho '542).

In ref to claim 64:

The one or more characteristics associated with the respiration comprises a duration of disordered breathing (Col. 3, lines 24-30 of Cho '542).

In ref to claim 67:

The one or more characteristics associated with the respiration comprises minute ventilation (Col. 7,lines 33-46 of Cho '542).

In ref to claims 71 & 72:

The respiration processor is configured to detect the one or more characteristics associated with the respiration based on physiological conditions or contextual conditions (Col. 8, lines 3-19 of Cho '542).

In ref to claims 78 & 84:

A communication device configured to transmit information about at least one of the respiration waveform, the one or more characteristics associated with the respiration, and the marked respiration waveform (telemetry interface 350 of Cho '542).

In ref to claims 80 & 86:

A memory configured to store information about at least one of the respiration waveform, the one or more characteristics associated with the patient respiration, and the marked respiration waveform (memory unit 330 of Cho '542).

11. Claims 43, 45 & 79 & 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 6,641,542 to Cho et al (Hereinafter "Cho '542") and in view of US Pub. No. 2002/0193839 to Cho et al (Hereinafter "Cho '839") and further in view of US Pat. No. 6,770,022 to Mechlenburg et al (Hereinafter "Mechlenburg").

In ref to claims 43 & 45 & 79 & 85:

Cho '542 and Cho '839 teach all the limitations of claims 38 & 81, see the rejection above.

However, Cho '542 and Cho '839 do not teach:

The component of at least one of the respiration waveform sensor, the respiration processor, and the waveform generator is

mechanically coupled to a positive airway pressure device, and the respiration waveform sensor comprises an airflow sensor. A display configured to display the marked respiration waveform.

Mechlenburg, teaches:

A device and method for magnetic stimulation of muscles for the diagnosis and relief of a breathing disorder, such as obstructive sleep apnea. The input signal indicative of the condition of a patient can be provided to a display device (Col. 5, lines 52-65 of Mechlenburg). Using the magnetic stimulating system in conjunction with a conventional pressure support system that applies positive air pressure at the mouth and/or nose of the patient (Col. 15, lines 58-67 & Col. 19, lines 38-49 of Mechlenburg). The onset of an upper airway event can be detected using an airway sensor (Col.8, lines 17-25 of Mechlenburg).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to have included the display system, airway sensor and the positive pressure control system of Mechlenburg in the sleep respiration treatment system of Cho '542, in order to display the signals for monitoring the patients conditions and measuring the airway pressure and positive pressure control system as part of the diagnosis and treatment for breathing disorders, as it has been explicitly taught by Mechlenburg.

***Allowable Subject Matter***

12. Claim 51 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. The following is a statement of reasons for the indication of allowable subject matter: Claim 51; claims that the respiration processor comprises a disordered breathing processor, the closest reference found only discloses one processor for processing input data, therefore claim 51 is an allowable subject matter.

Decent

***Conclusion***

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Pub. No. 2005/0119711 to Cho et al has been cited because it discloses an apparatus for monitoring disordered breathing. US Pub. No. 2003/0195571 to Burnes et al has been cited because it discloses an apparatus for treatment of central sleep apnea. US Pat. No. 7,081,095 to Lynn et al has been cited because it discloses a system for automatic diagnosis of obstructive sleep apnea. US Pat. No. 6,251,126 to Ottenhoff et al has been cited because it discloses an apparatus for treatment of obstructive sleep apnea.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anita Saidi whose telephone number is 571-270-3001. The examiner can normally be reached on Monday-Thursday 8:30 am - 7:00 pm Est..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chuck Marmor can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AS 7/16/07